REMARKS

Claims 1, 8, 12, 14, 15, and 19 are amended herein. Claim 21 has been cancelled. No claims have been added. **The claims remaining in consideration are claims 1-20.** Claims 1, 8, 12, 14, 15, and 19 are the independent claims remaining under consideration. No new matter has been added by this amendment and response.

I. Rejections Under 35 U.S.C. §102

The Examiner has rejected claims 1, 4, 6, 8, 10, 11, 15, 16 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,416,777 to Yaacobi ("the '777 patent"). The applicant requests reconsideration of this rejection.

The '777 patent discloses an ocular implant for localized delivery of a pharmaceutically active agent. '777 Patent, col. 1, lines 9-14. Unlike the applicant's claimed invention, the implant is a one-piece design that cannot be refilled. Id. at Figs 7-21. Once the inner core (81), comprised of the pharmaceutically-active agent, is expended, the entire device must be removed. Id. at col. 8, lines 59-60. An entirely new device with a new inner core must then be sutured to the eye in order to continue treatment.

In contrast, the applicant's implant does away with this need for invasive procedures to completely remove and replace an entire implant in order to continue treatment. The two-piece design of the applicant's design provides for the required securing sutures via the insert stabilizer portion while allowing ready removal of the implant portion. The implant can then be refilled and easily reconnected to the insert stabilizer without any need for additional suturing. The design of the applicant's device provides these novel features regardless of whether the desired pharmaceutical agent is in solid, powder, or fluid form. This represents a significant treatment advantage over the prior art, including the implant of the '777 patent, which, as explained above, must be removed in its entirety and replaced with a brand new implant that must itself be sutured in position.

The removable and refillable nature of the applicant's device was clearly claimed and described as presented in the applicant's original claims. Therefore, the '777 patent is not an appropriate §102(b) reference because it fails to identically describe each and every element of the rejected claims. *See Atlas Powder v. E.I. duPont*, 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984). For the sake of additional clarity, the applicant has amended claims 1, 8, 12, 14, 15, and 19 to further emphasize this feature of the claimed device.

Based on the foregoing, it is clear that the '777 patent does not disclose or suggest key elements of independent claims 1, 8, and 15 and cannot support a proper rejection under 35 U.S.C. §102. Dependent claims 4, 6, 10, 11, and 16 include the limitations of independent claims 1, 8, and 15, respectively, and are, therefore, at least similarly allowable over the '777 patent. The applicant respectfully requests reconsideration of this rejection.

II. Rejections Under 35 U.S.C. §103

A. Rejection Of Claims 2, 9, And 14 Over The '777 Patent And The '829 Publication

The Examiner has rejected claims 2, 9, 14, and 21 under 35 U.S.C. §103(a) as being unpatentable over the '777 patent in view of U.S. Published Patent Application 2004/0198829 to Sponsel et al. ("the '829 publication"). The applicant has cancelled claim 21 elsewhere in this response, and, therefore, the rejection of claim 21 is rendered moot. However, the applicant requests reconsideration of this rejection with respect to claims 2, 9, and 14.

As with the previous rejection, the Examiner cites the '777 patent as a primary basis for the rejection. However, as discussed in detail above, the '777 patent clearly fails to describe or even suggest a two-piece implant having a removable, refillable, and reattachable portion to enable ready continuation of ongoing trans-scleral therapy. These features are elements of independent claim 14 and also of claims 1 and 8, from which claims 2 and 9 depend. The '829 publication discloses the use of prostanoids as an effective transport enhancement into the eye for therapeutic agents. The '829 publication does not address or suggest a preferred structure for an ocular implant in any manner whatsoever. Therefore, it is unable to address the deficiencies of

the '777 patent discussed above. As such, the combination of the '777 patent and '829 publication do not disclose or suggest a two-piece implant having a removable, refillable, and reattachable portion as claimed by the applicant. Therefore, the applicant respectfully submits that claims 2, 9, and 14 are patentable over the combination of the '777 patent and '829 publication.

B. Rejection Of Claims 3, 5, 7, 12, 13, 17, 18, 19, And 20 Over The '777 Patent In View Of The '829 Publication And The '806 Publication

The Examiner has rejected claims 3, 5, 7, 12, 13, 17, 18, 19, and 20 under 35 U.S.C. §103(a) as being unpatentable over the '777 patent in view of the '829 publication and U.S. Published Patent Application 2005/0113806 to De Carvalho et al. ("the '806 publication").[1] The applicant also requests reconsideration of this rejection.

Once again, the Examiner cites the '777 patent as a primary basis for the rejection. Therefore, the applicant refers the Examiner to the specific comments above concerning the deficiencies of the '777 patent with respect to the claimed invention. In short, the '777 patent does not describe or suggest a two-piece implant having a removable, refillable, and reattachable portion to enable ready continuation of ongoing trans-scleral therapy as required in the independent claims of the present application, including claim 12. Furthermore, each of claims 3, 5, 7, 13, 17, 18, 19, and 20 depend from one of the independent claims reciting this feature. Therefore, in order to render those claims obvious, the combined cited references must disclose or suggest such a feature. They clearly do not.

The combination of the '777 patent and the '829 publication has been addressed by the applicant in the immediately preceding section. Once again, the '829 publication, which does not disclose, describe, or even suggest an implant structure can not cure the deficiencies of the '777 patent. The '806 publication also fails to address these deficiencies. The '806 publication

[1] The Examiner failed to formally cite the '777 patent in the introduction to this rejection. However, the applicant can only presume that the Examiner intended to so cite the '777 patent based on her reliance on this reference in the description of the grounds of rejection.

discloses a one-piece medical device having a reservoir with a release port that is held in position against the tissue to be treated by a sealing surface. '806 Publication, ¶[0066]. An alternate embodiment having a refill port that communicates with the reservoir. Id. As with the device of the '777 patent, the entire device of the '806 publication is usually sutured, or adhered, to the sclera. Id. at ¶[0068]. In addition, the device of the '806 publication is not compatible with solid form agents.

Therefore, the combination of the '777 patent, the '829 publication, and the '806 publication do not disclose or suggest a two-piece implant having a removable, refillable, and reattachable portion as claimed by the applicant. Therefore, the applicant respectfully submits that claims 3, 5, 7, 12, 13, 17, 18, 19, and 20 are patentable over the '777 patent, the '829 publication, and the '806 publication, either alone or in combination.

III. Conclusion

It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Response is respectfully requested.

Respectfully submitted,

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